OHIOHEALTH RESEARCH INSTITUTE
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Study Title: Exploratory Trial to Improve Postextubation Management for Patients at Risk for Extubation Failure

IRB Protocol Number: 1332767

Principal Investigator: Kiran Devulapally, MD

Study Sponsor: None

Overview of Participation in Research

If you are the Legally Authorized Representative (LAR) for the patient, we would like to ask your permission to include your dependent/loved one in this study. Throughout the remainder of this consent form, the term "you" refers to the patient.

- We are conducting a clinical trial (a type of research study), which includes only participants who voluntarily choose to take part in the research study. You are being asked to take part in this study because you are a patient on mechanical ventilation (i.e., with a breathing tube) and you have existing heart or lung disease.
- The purpose of the study is to see if we can make it easier for you to breathe on your own after your breathing tube is removed, and involves the administration of oxygen through face masks after your breathing tube is removed.
- If you choose to participate, your participation will involve approximately 24 hours over the course of your hospitalization.
- Because the results of the research are unknown, participation in research includes risks. If you choose to participate in the research, you may experience physical risks, which will be described in further detail below.
- You may or may not experience direct benefit from participating in this study. This may include a lower (smaller) chance that you will need to have a breathing tube again. Even if you do not experience any benefit, in the future we may be able to identify better ways to care for patients that need a breathing tube.
- You can choose not to participate in this study without penalty or loss of benefit.

1. What is involved if I participate in this study?

Reason for Conducting the Research: The reason we are conducting this study is because patients that have long-lasting heart or lung issues may find it hard to breathe on their own after they have been on a mechanical ventilator (a machine operated breathing tube). When this happens, they may need to be placed back on the ventilator.

Description of the Research Procedures: If you participate in the study, you will be given oxygen in two, non-invasive ways after your breathing tube is removed. Non-invasive means that the air is given to you externally, via a mask. The first way is called **B**iLevel **P**ositive **A**irway **P**ressure, or BiPAP. During BiPAP, you wear a mask or nasal plugs, and the machine pushes air into your lungs. The second way is called **H**eated **H**igh **F**low **N**asal **C**annula **O**xygen, or HFNC. During HFNC, heated, humidified (moist) air is pumped into your nose through two small, flexible tubes.

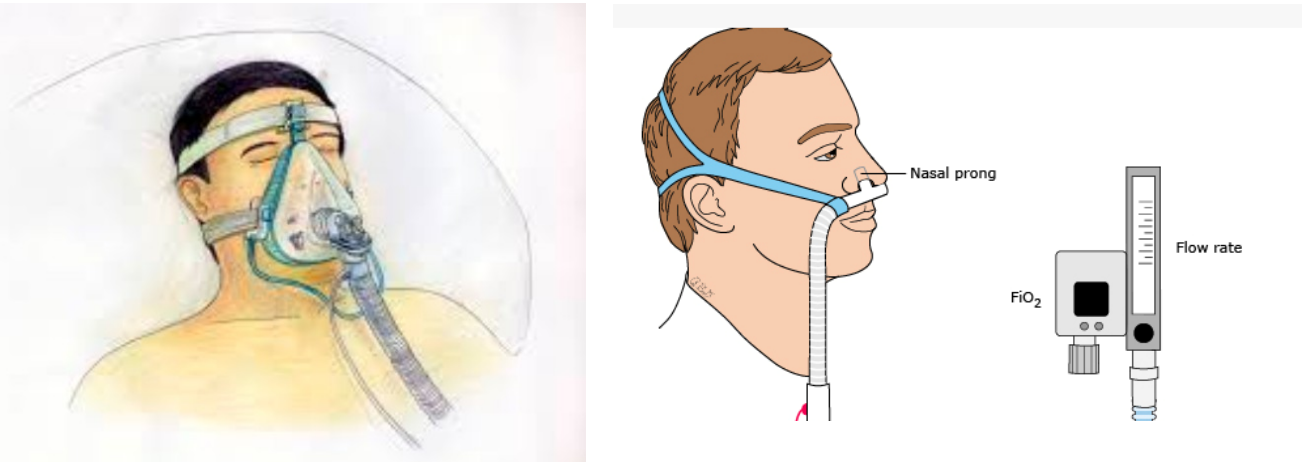

Figure 1. Picture showing how the BiPAP mask (left) and HFNC nasal cannula (right) fit over the nose and face.

We will place a BiPAP mask on you after we remove your breathing tube. As long as you're comfortable, we will leave the mask on you for about 2 hours. We will then remove the BiPAP mask and replace it with the HFNC tubes. We will continue switching BiPAP and HFNC about every 2 hours while you are awake, and we will give you air by BiPAP overnight while you're asleep. In the morning, we will remove you from BiPAP.

All patients that have their breathing tubes removed may be given oxygen by their doctor, including through BiPAP and HFNC. What is special about this research project is that we will give you both types of air, switching back and forth for 1 day after your breathing tube is removed.

Participation in Research is Voluntary: You can stop being a part of this study at any time. If you do choose to stop participating, you may want to consult with the researchers to discuss other choices outside of the research.

Options Instead of Participating in the Research: Instead of being in this study, you have the following options:

- You may receive oxygen according to your doctor's standard of care, which may include BiPAP and/or HFNC
- You may get other treatment even if you do not take part in the study.

Before you make a decision about participating, please take the time to discuss your decision about participating with the researchers, your doctor, your friends or family, or others. If you have any questions about what is involved with the study, please ask the researchers so you can make an informed decision.

Number of People Participating in this Study: There are expected to be 40 participants enrolled into this study overall. All participants will be enrolled at OhioHealth Grant Medical Center.

2. *What bad things might happen if I participate in this research?*

Risks of Participating in the Research: There are always risks of participating in research. Some are minimal risk that could happen even if you do not participate, such as breach of confidentiality and risks associated with BiPAP or HFNC including:

- swallowing air, which can be uncomfortable;
- agitation or delirium;
- feelings of claustrophobia;
- congestion; and
- dry mouth, nose, and/or throat.

These risks are common, mild in severity, and reversible.

Other risks can be more serious, these risks include:

- Breathing difficulty

You can experience these risks regardless of whether or not you participate in the study, and we do not anticipate that participating in the research increases this risk.

Potential Risks to Unborn Babies: There are no expected risks to unborn babies if you are pregnant.

Ending Participation in the Study: Your study doctor may decide to take you off this study if you do not tolerate BiPAP or HFNC. Participation is completely voluntary. However, if you decide to stop being in the study, please talk to the researchers first.

New Information Affecting Willingness to Continue Participation: You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.

Information Relevant to Future Treatment: If the researchers discover information that may have an impact on your non-research related medical treatment, this information will be shared with the physicians treating you during your hospital stay if we believe that the information is of urgent medical importance. This information will be shared because it may have an impact on your non-research related medical treatment.

Questions, Concerns, or Complaints Related to the Study: If you have questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Dr. Kiran Devulapally at 614-566-9143.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Human Subjects Protections at 614-566-1748.

3. Are there any potential benefits I might experience by participating in the study?

Potential for Direct Benefit: If you agree to take part in this study, there may or may not be direct benefit to you. If you participate, you may be able to breathe easier after your breathing tube is removed, which may reduce the chance that you will need to have the breathing tube put back in. The researchers cannot guarantee whether or not you will experience direct benefit.

Potential Benefit to Others in the Future: Even if you do not receive any direct benefit, the researchers hope that the information from this study will result in better treatments for patients that need breathing tubes in the future.

4. *Are there any costs that I will have to pay to participate in the study?*

Costs of Participating in the Research: Sometimes there are costs associated with participating in research. It is not expected that participation will cost anything more than your time.

Cost of Medical Procedures for Research: While you are in this study, you may have tests, procedures, and exams that are part of your routine medical care. The expense for routine medical care will not be paid for by the study and will be billed to your medical insurance.

If your medical insurance does not pay for this routine medical care, you will be billed for the cost of medical care related to your condition, including but not limited to tests, deductibles, co-payments, study doctor and clinic fees, hospitalization and procedures.

Payment for Harm Caused by the Research: In the case of physical, psychological, or other harm resulting from this study, emergency medical treatment will be provided as necessary. You or your insurance company will be financially responsible for this emergency medical treatment, continuing medical care and/or hospitalization. OhioHealth Corporation has no funds set aside to compensate you in the event of injury or illness.

5. *Will I be paid for taking part in this research study?*

You will receive no payment for taking part in this study.

6. *Will information or biological samples (e.g., blood, urine, etc.) be collected from me?*

Information Collected for the Research: We will collect personally identifiable information from you that will be used in the research and kept confidential, as described below.

Biological Samples Collected for the Research: We will not collect any biological samples from you for the purposes of the research.

Future Use of Information: In the future, your information collected for this study might be shared with other researchers. If we do this, you will not have an option to consent to the future research, whether or not to share your information with other researchers or use your information for future research studies, even if all of the information that can identify you personally has been removed.

7. *Who will be able to access information about me and will it be kept confidential?*

What information may be used and given to others?

The study doctor or study staff will have access to your personal and medical information. For example:

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research study;
- Records about the study treatment you received;
- Information that may include your name, address, telephone number, social security number, date of birth or a number associated with you as an individual

Who might have access to this information?

- Your study-related information may be placed in your permanent medical record, clinic or doctors' office records.
- Authorized OhioHealth staff not directly involved in the study may be aware that you are participating in a research study and have access to your information.

Your information <u>may</u> be given to parties, such as:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Representatives of governmental financial agencies,
- OhioHealth Corporate Ethics and Compliance
- OhioHealth Office of Research Compliance
- OhioHealth Institutional Review Board (IRB)
- OhioHealth Office of Human Subjects Protections
- OhioHealth Data Safety and Monitoring Board (DSMB)

Why will this information be used and/or given to others?

- To do the research study,
- To study the results, and
- To see if the research study was done properly.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to take part in this research study.

May I review or copy my information?

While the research study is in progress, your access to your study records will be temporarily suspended. You may review or copy your information after the study is complete.

May I withdraw or revoke (cancel) my permission?

You may withdraw or take away your permission to use and disclose your health information at any time. You may do this by sending a written request to the study doctor at:

Kiran Devulapally, MD
Medical Director, Critical Care Unit Pulmonary Services
111 South Grant Avenue
Columbus, OH 43215

If you withdraw your authorization:

- Your participation in the study will end
- The study staff will stop collecting your medical information
- Information that has already been gathered may still be used and given to others.

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Is my health information protected after it has been given to others?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Once your information is disclosed to the IRB or the government agencies described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by federal privacy regulations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the OhioHealth Corporation Office of Ethics and Compliance at 614-544-4200.

Statement of Consent and HIPAA Research Authorization

I hereby freely and voluntarily consent to take part in the research study described above. This consent is given based on the verbal and written information provided and the understanding that I am medically and physically qualified to take part in this study. I am free to ask questions at any time.

I have the option to decline to take part or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available, including medical care at this institution.

My signature below indicates that I voluntarily agree to take part in this study and that I authorize the use and disclosure of my information in connection with the study. I will receive a signed copy of this consent and authorization form.

Participant / Legally Authorized Representative

_____	_____	_____
Printed Name of Participant	**Signature of Participant***	**Date / Time**
_____	_____	_____
Printed Name of Legally Authorized Representative	**Signature of Legally Authorized Representative**	**Date / Time**

Investigator / Research Staff

_____	_____	_____
Printed Name of Person Obtaining Consent	**Signature of Person Obtaining Consent**	**Date / Time**
_____	_____	_____
Printed Name of Investigator	**Signature of Investigator**	**Date / Time**

Witness (if applicable)

_____	_____	_____
Printed Name of Witness	**Signature of Witness**	**Date / Time**

*If this consent is signed by a legal representative of the patient, check applicable box below explaining your authority to sign for the patient.

☐ Next of Kin

☐ Health Care Power of Attorney (legal documentation required)

☐ Health Care Proxy or Surrogate (legal documentation required)

If the patient is participating but unable to give consent, indicate why.

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_____

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REGAINED CAPACITY CONSENT FORM

Because your illness or injury made it impossible for you to participate fully in the informed consent process, the consent was obtained from your legally authorized representative (surrogate) on your behalf. Your legally authorized representative believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research project.

Informed consent is essential throughout a research project. This means in your situation, you are now being given the opportunity to agree or disagree with the decision made by your legally authorized representative for you to participate. Any information that has already been obtained, when the researchers were acting on your legally authorized representative's consent for you involvement, will remain part of the study information, but it is now your choice whether to continue.

Please check the appropriate box to indicate your decision:

☐ I wish to remain in the study.

☐ I wish to withdraw from the study.

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Dr. Kiran Devulapally at 614-566-9143.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Human Subjects Protections at 614-566-1748.

_____	_____	_____
Printed Name of Participant	**Signature of Participant**	**Date / Time**
_____	_____	_____
Printed Name of Person Obtaining Consent	**Signature of Person Obtaining Consent**	**Date / Time**